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Recently Published Study Shows Positive Results for ZiNGO® in Pediatric Patients

11 September 2015, Hong Kong - Lee's Pharmaceutical Holdings Limited ("Lee's Pharm" or the "Group", Stock Code: 950) an integrated research-driven and market-oriented pharmaceutical group in China is pleased to announce that Powder Pharmaceuticals Incorporated ("PPI"), an associated company of the Group, has a recent publication of a clinical study¹ confirmed that ZiNGO® (lidocaine hydrochloride monohydrate, 0.5 mg) powder intradermal injection system significantly reduces venous access pain in pediatric patients. The results were published in the journal *Clinical Therapeutics*.

This announcement is co-released with Marathon Pharmaceuticals, LLC, PPI's exclusive licensee, distributor, marketer, advertiser, promoter, importer and seller of ZiNGO® in the United States.

ZiNGO® is a fast acting, easy to use, sterile, needle-free product that, with the push of a button, delivers a 0.5 mg dose of powdered lidocaine particles into the skin numbing the site in just one to three minutes. ZiNGO® is currently in use at several major children's hospitals nationwide.

The phase III, randomized, double-blind, placebo-controlled study collected data from 535 patients of ages 3-18. Study subjects represented a broad spectrum of pediatric patients, including those in outpatient as well as inpatient settings, who were undergoing venipuncture or peripheral venous cannulation procedures as part of their standard clinical care. The active system group had significantly ($P=0.0022$) less pain compared with the placebo in all age groups combined.

Venous access procedures were performed successfully on the first attempt in 95.5% of the patients in the active treatment group and 96.2% in the placebo group, suggesting that ZiNGO® did not negatively impact the ability to access the vein. The most commonly observed adverse reactions were nausea and vomiting. The incidence of treatment-related adverse events was similar in both treatment groups: 1.9% in the active group and 1.5% in the placebo group. No patient experienced a serious adverse event. There were no reports of vasoconstriction in patients in either group.

Analgesic efficacy was assessed by patient self-report of venous access pain (Wong-Baker FACES Pain Rating Scale [3–18 years] and visual analog scale [VAS; 8–18 years]) and parental observational VAS. Safety measures included adverse events (AEs) and skin assessments.

"This study confirms that ZiNGO® is an easy-to-administer, fast-acting, safe and effective, needle-free topical local anesthetic that can be easily incorporated into the busy health care environment," said William T. Zempsky, MD, Professor of Pediatrics and Division Head of Pain and Palliative Medicine at Connecticut Children's Medical Center, and an author of the study.

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“Because commonly available local anesthetic products can take up to 30 to 60 minutes to work, making incorporation into the busy healthcare environment difficult, healthcare providers have had to sacrifice patient comfort when performing the numerous venous access procedures that occur each day. ZiNGO® can be a source of needed relief to children and parents,” Zempsky said.

About ZiNGO®

ZiNGO® (lidocaine hydrochloride monohydrate) is an amide local anesthetic indicated for use on intact skin to provide local analgesia prior to venipuncture or peripheral intravenous cannulation in children 3–18 years of age and to provide topical local analgesia prior to venipuncture in adults. The rapid onset of analgesia in 1-3 minutes provides care givers and patients the opportunity for a pain-free and needle-free access procedure. Clinical trials have shown a statistical difference in pain scores during needle access procedures when using **ZiNGO®** versus a placebo system. **ZiNGO®** is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type. It is not to be used around the eyes or on body orifices, mucous membranes, or on areas with a compromised skin barrier.

ZiNGO® should only be used on skin locations where an adequate seal can be maintained. Adversereactions in clinical studies of **ZiNGO®** primarily included application-site reactions (i.e., hypoaesthesia, burning, and venipuncture site hemorrhage) and dizziness (which occurred in 0.9% of active treated subjects vs. 0.7% of those administered placebo).

About Lee's Pharmaceutical Holdings Limited (“Lee’s Pharm”)

Lee’s Pharm is a research-based biopharmaceutical company listed in Hong Kong with over 19 years operation in China's pharmaceutical industry. It is fully integrated with strong infrastructures in drug development, manufacturing, sales and marketing. It has established extensive partnership with over 20 international companies and currently has 14 products in the market place. Lee's Pharm focuses on several key disease areas such as cardiovascular, oncology, gynecology, dermatology and ophthalmology. Lee's Pharm development program is lauded with 30 products stemming from both internal R&D efforts and collaborations with US, European and Japanese companies and aspiring to combat diseases such as liver cancer and pulmonary hypertension. The mission of Lee's Pharm is to become a successful biopharmaceutical group in Asia providing innovative products to fight diseases and improve health and quality of life.

Additional information about Lee’s Pharm is available at www.leespharm.com.

About Powder Pharmaceuticals Incorporated (“PPI”)

PPI is an associated company of Lee’s Pharmaceutical Holdings Limited based in Hong Kong and is developing products that utilize a proprietary needleless, painless, powder delivery technology. PPI intends to supply ZiNGO® globally through international business partners. PPI has successfully obtained approval from U.S. FDA in July 2013 for the manufacturing facilities in Hong Kong to produce ZiNGO® and market the product to U.S.

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About Marathon Pharmaceuticals, LLC (“Marathon”)

Marathon Pharmaceuticals, LLC is a leader in the development, manufacturing and commercialization of specialty pharmaceutical drugs to treat rare diseases for high need patient populations. Marathon is a rapidly growing U.S. based company and has multiple marketed products to complement its early and late stage clinical development programs. Marathon is headquartered in Northbrook, Illinois.

Additional information about Marathon is available at www.marathonpharma.com.

REFERENCES:

1. Schmitz ML, Zempsky WT, Meyer JM. Safety and Efficacy of a Needle-Free Powder Lidocaine Delivery System in Pediatric Patients Undergoing Venipuncture or Peripheral Venous Cannulation: Randomized Double-Blind COMFORT-004 Trial. ClinTher. 2015 Jul 8. [Epub ahead of print]

Safe Harbor Statement

The performance and the results of operation of Lee's during the past years are historical in nature and past performance can be no guarantee of future results of the Lee's. This news release may contain forward-looking statements and opinions that involve risks and uncertainties. Actual results may differ materially from expectations discussed in such forward-looking statements and opinions. Neither Lee's nor the Directors, employees or agents of Lee's assume (a) any obligation to correct or update the forward-looking statements or opinions contained in this news release; and (b) any liability in the event that any of the forward-looking statements or opinions does not materialise or turns out to be incorrect.

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